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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,949	07/31/2003	Masahiro Ishima	03461C/HG	5027

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,949	ISHIMA ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 22, 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen of Group Art Unit 1648.

2. Applicant's preliminary amendment filed January 22, 2004 is acknowledged. Claims 1-23 are pending and are subject to the following restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1, 2, 4, 6, 8, 10-12, 14, 15 link(s) inventions I, II, III, IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 4, 6, 8, 10-12, 14, 15. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

I. Claim 3, drawn to a peptide or a salt thereof, classified in class 530, subclass 300.

II. Claim 5, drawn to a peptide or a salt thereof, classified in class 530, subclass 300.

III. Claim 7, drawn to a peptide or a salt thereof, classified in class 530, subclass 300.

IV. Claim 13, drawn to a peptide or a salt thereof, classified in class 530, subclass 300.

V. Claim 16, drawn to a peptide or a salt thereof, classified in class 530, subclass 300.

Claim 17 links inventions VI, VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 17.

VI. Claim 17, drawn to a method of preparing a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, a method comprising culturing at least one strain capable of producing peptides of groups classified in class 530, subclass 412.

VII. Claim 17, drawn to a method of preparing a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 3 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, a method comprising culturing at least one strain capable of producing peptides of groups classified in class 530, subclass 412.

VIII. Claim 17, drawn to a method of preparing a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydec-5-enoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, a method comprising culturing at least one strain capable of producing peptides of groups classified in class 530, subclass 412.

Claims 19-21 links inventions IX, X, and XI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 19-21.

IX. Claim 18, drawn to a strain belonging to genus *Pseudmonas,* wherein the strain is capable of producing a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-

hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 300.

X. Claim 18, drawn to a strain belonging to genus *Pseudmonas,* wherein the strain is capable of producing a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 3 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 300.

XI. Claim 18, drawn to a strain belonging to genus *Pseudmonas,* wherein the strain is capable of producing a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydec-5-enoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 300.

XII. Claim 22, drawn to an antiviral agent comprising a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 300.

XIII. Claim 22, drawn to an antiviral agent comprising a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 3 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 300.

XIV. Claim 22, drawn to an antiviral agent comprising a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydec-5-enoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 300.

XV. Claim 23, drawn to a method of preventing and treating a subject infected with a virus, wherein the method comprises administering to the subject the antiviral agent comprising a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 412.

XVI. Claim 23, drawn to a method of preventing and treating a subject infected with a virus, wherein the method comprises administering to the subject the antiviral agent comprising a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 3 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydecanoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 412.

XVII. Claim 23, drawn to a method of preventing and treating a subject infected with a virus, wherein the method comprises administering to the subject the antiviral agent comprising a peptide having as constitutive amino acids, 4 glutamine-derived amino acid residues, 1 glutamic acid residue, 1 serine residue, 2 valine residues, 1 isoleucine residue and 5 leucine residues, and having a 3-hydroxydec-5-enoyl group that is bonded, via an amine linkage, to the N-teriminal leucine residue thereof, classified in class 530, subclass 412.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions (I, II, III, IV, V) and (VI, VII, VIII) are related as product and process of use. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of groups (I, II, III, IV, V) can be made by another materially

different process other than using the method comprising culturing at least one strain capable of producing peptides of groups (I, II, III, IV, V). For example the peptides can be made synthetically. Furthermore, the three polypeptides are different structurally and must be searched not only in commercial amino acid sequence databases, but also in textual databases of non-patent literature. Searching all polypeptide sequences together would present a serious search burden on the Office. The inventions (I, II, III, IV, V) and (VI, VII, VIII) have a separate status in the art as shown by their different classifications. Therefore restriction for examination purposes is proper.

Inventions (I, II, III, IV, V) and (IX, X, XI) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination has utility by itself or in other combinations. The subcombinations, such as the polypeptides of group (I, II, III, IV, V) and the bacterial strain belonging to genus *Pseudomonas* producing polypeptides of group (IX, X, XI) have separate utility such as the polypeptides can be used in the method of immunization against viral or bacterial disease and Pseudomonas can be used as an agent for both biodegradation and biocontrol, and as a plant-growth-promoting bacterium.

Inventions (I, II, III, IV, V) and (XII, XIII, XIV) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the

combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination has utility by itself or in other combinations. In the instant case, the combination, the antiviral agent, as claimed does not require the particulars of the subcombination, the polypeptides, as claimed because the subcombination specifies particular polypeptides. The subcombination has separate utility such as in a method to induce an immune response.

Inventions (I, II, III, IV, V) and (XV, XVI, XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of preventing and treating a subject infected with a virus can be practiced with another materially different product other than administering the antiviral agent comprising the polypeptides of group (I, II, III, IV, V). For example the viral infection can be treated with a drug such a Ribavirin.

Inventions (VI, VII, VIII) and (IX, X, XI) are related as product and process of use. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of preparing the peptides using *Pseudomonas* strain can be practiced

with another materially different product for example the peptides can be make by process of peptide synthesis using peptide synthesizer.

Inventions (VI, VII, VIII) and (XII, XIII, XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01 In the instant case, the different inventions, the antiviral agent is not disclosed as being used in the methods of preparing the peptides using growing *Pseudomonas*, and the different inventions have different modes of operation such as a antiviral treatment mode of operation of group (XII, XIII, XIV) which is different from the polypeptide preparation of group (VI, VII, VIII). The literature search, required for group (VI, VII, VIII) regarding the method of preparing polypeptides would not necessarily reveal the literature regarding the antiviral agents, of group (XII, XIII, XIV). It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes is proper.

Inventions (VI, VII, VIII) and (XV, XVI, XVII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to two different methods, a method of preparing the polypeptides and a method of treating and preventing viral disease. A search for a method of preparing the polypeptides, is not co-extensive with a search for a method of

preventing and treating viral disease In addition even though in some cases the classification is shared, the different search would be required based upon the different method steps used.

Inventions (IX, X, XI) and (XII, XII, XIV) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination has utility by itself or in other combinations. The subcombinations, such as the polypeptides produced by the strain of group (IX, X, XI) and the antiviral agent of group (XII, XII, XIV) have separate utility such as the polypeptides can be used in the method of immunization against viral or bacterial disease and the viral agent can be used the test its cytotoxic effect on virally infected cells *in vitro*.

Inventions (IX, X, XI) and (XV, XVI, XVII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions, the single peptides alone produced by Pseudomonas strain are not disclosed as being used in the methods of treating and preventing viral disease. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes is proper.

Inventions (XII, XII, XIV) and (XV, XVI, XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of preventing and treating a subject infected with a virus can be practiced with another materially different product other than administering the antiviral agent of group (XII, XII, XIV). For example the viral infection can be treated with a drug such a Ribavirin.

Because the inventions are distinct for the reasons given above and the literature and sequence search required for one group is not co-extensive with any other group, and therefore presents a serious burden of search, restriction for examination as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Notice of Possible Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen, Ph.D. whose telephone number is 571-272-8035. The examiner can normally be reached on M – F (9:00AM – 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.
April 7, 2006

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